

REMARKS / ARGUMENTS

By the Official Action dated 10/07/03, claims 1-51 stand rejected.

-TM 7-20-D4

{ In this Amendment B, all pending claims have been amended. Claims ^{2,} ~~1, 3-29,~~ 30-32, 50 and 51 have been cancelled. Thus, claims ~~1-29,~~ ^{2,} 33-49 remain in this application. Figures 1, 2, 3, 4, 5, 6, and 7 have also been amended to comply with the specification.

Substitute drawing pages are submitted herewith.

1. Concerning the objections to the drawings raised by the examiner, Figure 5 has been amended to add reference numeral 450.
2. Headings have been added to the specification per 37 CFR 1.77.
3. Applicant thanks the Examiner for his observations on the final paragraph of the specification. These comments will be taken under advisement.
4. Concerning to the informalities raised by the examiner:
 - a. Regime has been amended to "regimen";
 - b. The periods following numerals on Page 12, 13, 15, 16 have been deleted;
 - c. The description of Figure 5 on Page 12 has been amended to delete reference to the third system;
 - d. The second occurrence of "Figure 2" on Page 13, line 29, has been amended to "Figure 1";
 - e. The various instances of typographical errors on pages 14, 17 and 18 concerning "e.g." and "i.e." have been corrected via amendment; and
 - g. The first occurrence of "by" on Page 14, line 29 has been deleted.
 - h. The phrase "s the" has been corrected to --as the-- on page 17, line 27.
5. In response to the issues raised by the examiner in the drawings, applicant points out the following:
 - a. Figure 1. has been amended to depict the subject matter described in the text of the specification, i.e., an electronic data management system 13,

comprising in part a transmitter 18. The transmitter can also be depicted, for example, as a "display driver" 632 in Figure 7, which transmits a display signal to the display. The "communicator" is depicted as variously as 40, 140 and 640. no new matter has been added hereby;

- b. The "coupling mechanism" objection is moot, as claim 50 has been deleted;
- c. The "gateway" as in claim 5 is depicted as new feature 52 in Figure 1, and 152 in Figure 2. The basis for this language is supported by the summary and claims of the original application. The Specification on pages 13 and 14 have been amended to reflect these features. No new matter is added by these amendments;
- d. "embedded network server" is depicted as ref number 554 in Fig 6, and 654 in Figure 7. The drawings are hereby amended to conform with the text of the specification, including the claims;
- e. As will be appreciated by one of ordinary skill reading the specification, "cellular phone" or "pager", may be a component(s) of "palmtop 170";
- f. "emergency assistance", "research establishment" are variables for the box depicted in Figure 1, as "OTHER REMOTE INFORMATION SOURCE(S)," ref. numeral 63;
- g. "local data store" is depicted as box 171 in Figure 2. The "personal computer" or "set top box" are variables for the local data store 171;
- h. As would be appreciated by those of ordinary skill, a "predicative algorithm" or a "look up table" may be information provided by the electronic management system. It is respectfully submitted that figure representing such data would not add to the understanding of those of ordinary skill in understanding the present invention. Withdrawal of such objection is requested as appropriate under the circumstances;

- i. Claims 30-32 have been cancelled, rendering the objections to the drawings on claims 30-32 (i.e. a "selector") moot;
- j. The drawings have been amended to show the "geographic positioning system" ref numeral 141 in Figure 2. The specification on page 14 has been amended to specify this amendment to the drawing. Basis for the amendments is found at Page 8, line 28, and in claim 34 as filed. No new matter is added by these amendments;
- k. The "breath-moveable element" is a possible variable for box ref. numeral 132 in Figure 2. Page 14 of the specification has been amended to refer to this amendment to the drawing. Basis for the amendment is found at Page 9, first paragraph and in claims 36 and 37. No new matter is added by these amendments;
- l. The "actuator" is depicted as box ref. numeral 133, in Fig. 2. The specification on page 13 has been amended to refer to this amendment to the drawing. Basis for the amendment is found for example at Page 9, line 30 and for example in claims 45 and 49. No new matter is added by these amendments;
- m. The "aerosol valve" is depicted as ref. numeral 134, in Fig. 2. The specification has been amended to refer to this amendment to the drawing. Basis for this amendment is found for example at Page 10, line 5 and for example in claims 47. No new matter is added by these amendments;

6. 35 USC 112, 2nd ¶ is Complied With

As explained below, in light of the amendments made to the specification, Claims 1-29, 33-49 comply with 112, Paragraph 2. As detailed below, the specification has been amended to address the instances raised by the examiner. Basis for such amendments are as indicated herein. No new matter is added hereby.

Claim 1 and all claims dependent thereon require a communicator 40, which communicates data to and from an electronic data management system (EDMS). As

set out in claim 1, the electronic data management system comprises a memory, a microprocessor, and a transmitter for transmitting for transmitting data. The EDMS communicates with a network of computers wirelessly through the communicator. Figure 1 has been amended to depict the EDMS 13, the memory 16, microprocessor 17 and transmitter 18 as three separate boxes within EDMS 13. As will be appreciated, one or more of these features may be integrated into one or more circuit chip(s). The detailed description of the specification has been amended on page 13 in the paragraph starting on line 9 in accordance with the language of claim 1 and the specification on page 3, lines 28-31. No new matter has been added thereby.

The description of Figure 2 on page 13 in the specification has been amended to clarify the separate identities of the communicator (a.k.a. communications transceiver 40, communications system 140) and the EDMS.

The specification, at page 14, second paragraph, states that in an alternative embodiment, a palmtop computer may be used to access the EDMS within dispenser 110. The paragraph has been amended to clarify the relationship of the component parts of the dispenser, and its relation to the palmtop.

Figures 3, 4 and 5 have been amended to more appropriately represent the dispenser 210, 310 and 410, which incorporates the electronic data management system. Pages 14-17 have been amended to appropriately identify the components referred to.

As abundantly established throughout the specification, the "data" referred to in claim 1 may originate either from the dispenser and be stored in the EDMS, or may have originated from an information source via the network, as would be understood by one of ordinary skill. Applicant asserts that the use of this term is both clear and concise within the meaning of 112, 2nd ¶. Withdrawal of the rejection on this ground is respectfully requested.

Comments directed toward claim 50 are moot in light of the cancellation of this claim.

Claim 14 has been amended to clarify what "thereto" refers.

In light of these clarifying amendments, it is asserted that one of ordinary skill would understand the metes and bounds of these claims, as required by 35 USC 112, 2nd ¶.

7. Claim 9 has been amended to correctly identify claim dependency.
8. **The Pending Claims are Novel over Bloomquist et al (US 5,338,157), Misheleich et al (US 5,363,842), Davis et al (US 5,544,661), Wolf (US 5,5809,997), and McKinnon et al. (US 6,202,642).**

The claims have been amended to recite a ‘portable device’ comprising ‘a housing’ i.e. as opposed to a ‘system’. It is submitted that basis for this amendment is provided throughout the application as originally filed, particularly at description page 3, lines 12-13 and at Figure 1.

Claim 1 has been amended to recite that the network computer system is ‘remote’ (i.e. geographically distant from the ‘device’). Again, it is submitted that basis for this amendment is provided throughout the application as originally filed, for example Figures 3 and 4 and description thereof at page 14, line 19 to page 15, line 20.

Claim 1 has further been amended include the feature of claim 2, as originally filed relating to ‘two-way transfer of data’.

The Examiner raised objections having regard to Bloomquist et al (US 5,338,157), Misheleich et al (US 5,363,842), Davis et al (US 5,544,661), Wolf (US 5,5809,997), and McKinnon et al. (US 6,202,642).

In view of the arguments presented below it is submitted that the claimed invention is novel and non-obvious over all of the cited documents.

a. Bloomquist, US 5,338,157

Bloomquist describes systems and methods for communicating with ambulatory medical devices such as drug delivery devices. It is submitted that described systems and methods are of a type designed for use at a fixed site local to the patient (e.g. see Bloomquist at column 6, lines 4-8 at column 8, lines 29-32).

By contrast, the claimed invention relates to a 'portable device' for the delivery of medicament' such as an inhaler device (e.g. see Figure 1) that would be carried around by a patient. The device of the claimed invention integrally comprises not only medicament container and dispenser features, but also an electronic data management system and a wireless communicator.

The claimed invention is therefore submitted to be novel over document Bloomquist because:

1. The systems and methods of Bloomquist are not designed for use with a 'portable device' carried by the patient but rather with apparatus for fixed use at a site local to the patient; and
2. The pump 40 and modem 48 that form the 'system' of Bloomquist are not comprised within an integral 'portable device'. Rather, these are described to be separate components connecting together to form a system (e.g. see document D1 at Figure 1 and column 8, lines 26-28) which describes cable connection of the pump 40 and modem 48.

It is accordingly submitted that Bloomquist does not clearly and unmistakably disclose the device of the claimed invention, as a whole.

For these reasons, Bloomquist also fails to anticipate claims 7, 8, 25, 26 and 27.

b. **Michelevich**

Michelevich describes an 'intelligent inhaler' that includes an electronic data management capability. The Examiner refers to column 6, lines 30-31 and col. 7,

lines 67-68 at which there is description of ‘communication to and from the clinical workstation in the office of the physician’ which can be via a ‘data connector socket’ (as in Figure 1) or ‘spatially remote control source’.

As described in Michelevich, the communication is to a ‘fixed location’ (i.e. the clinical workstation in the office of the physician). By contrast, the claimed invention requires ‘a communicator for wireless communication with a remote network computer system’. Thus, the communicator enables two-way transfer of data with a distributed ‘network’ (e.g. the Internet) rather being constrained to any single ‘fixed location’ workstation. The claimed invention is therefore submitted to be novel over the description of Michelevich.

By way of further explanation, it is noted than wireless communication with a network would be achieved by technically different and distinct means than ‘point-to-point’ communication to a single workstation. In particular, wireless communication in accord with the claimed invention might be enabled by either use of:

- (a) ‘an embedded network server’ within the device (claim 5); or
- (b) using ‘spread spectrum’ signals to communicate via a second communications device (claim 8) as described at Figure 2 and page 13, line 29 to page 14, line 17 of the description.

Neither of these means for enabling wireless communication with a network is described in Michelevich. It is accordingly submitted that Michelevich does not clearly and unmistakably disclose the wireless, network communication capability of the claimed invention. The claimed invention is therefore submitted to be novel over Michelevich.

For these same reasons Mishelevich fails to anticipate claims 25, 26, 27, 33 and 35.

c. Davis

Davis [provides only] does not describe a portable device comprising a housing containing the elements as claimed in claim 1. Further, Davis describes a "centralized system" with information downloaded to a central computer, rather than a network as claimed in the present invention.

The present invention claims portable device for the delivery of medicament comprising a *housing; received by said housing, a medicament container; associated with said medicament container, a dispensing mechanism for dispensing medicament from the medicament container; provided to the housing, an electronic data management system comprising: (i) a memory for storage of data; (ii) a microprocessor for performing operations on said data; and (iii) a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data.* Davis does not describe such a system. Instead, Davis provides a live feed of data & information concerning a patient's heart function to a remote clinician work station by way of a cellular system. The medicament delivery system is not within the housing of the electronic data management system. Because Davis does not describe the claimed invention exactly as claimed, it fails to anticipate the claims as amended.

For these reasons, Davis also fails to anticipate 7, 8, 25 and 26.

d. Wolf

Wolf describes a universal medication chronolog which "piggybacks" on a standard inhaler. The Wolf device record use information on an internal memory, and downloads this data an IR port to a peripheral cradle attached to a PC or directly into a PC. Uploading information to the device is also facilitated by the IR port. Thus Wolf described downloading/uploading to/from a work station, which then communicates to a clinical workstation. See col., 22lines 1-53. Wireless communication is not made from the Wolf device to the clinical workstation.

Thus, the deficiencies in Wolf are similar to those above for Davis. Wolf describes a local infra-red (col. 17, lines 4-6) download to a docking station (col. 22, lines 27-53) which can then connect to a network. This is different from the claimed invention

that is designed to enable wireless communications to a remote network, without any need for local download to a docking station.

For these same reasons, Wolf fails to anticipate claims 22, 23, 24, 27, 33 and 35.

e. **McKinnon**

As described in McKinnon [Col 3, line 42 to col. 4, line 7], the system described incorporates a medicine dispensing system 100, a docking station 300, a user computer 304, and a medical work station 308. The dispensing system 100 communicates wirelessly with the docking station 300, when docked therein. The docking station is coupled to a user computer 304, having a first modem. A medical workstation 308 has a second modem. The first and second modems communicate via phone line or internet to allow two-way transfer of data.

McKinnon, for these same reasons fails to anticipate claims 25, 26, 27, 33, and 35.

The McKinnon device, as with the Wolf system, allows the transfer of date via a docking station, as contrasted with the instant invention which allows data to be transmitted "on the move" via its wireless connection with the network computer system.

Having addressed each of documents listed above, withdrawal of all of the Examiner's objections in respect of the novelty of the claimed invention are respectfully requested.

9. The Examiner has failed to demonstrate Claims 3, 5, 6, 9-11, 34, 36-49 are Obvious

As mentioned above, portable device of claim 1 is novel over the prior art. For these same reasons, the examiner has failed to establish a case rendering the claims from which these select claims depend unpatentable. Claims 3, 5, 6, 9-11 and 34 and 36-49 are patentable for the same reasons.

Further, the claimed invention provides a portable device for the delivery of medicament that includes an electronic data management system. The claimed invention further provides that the device enables two-way transfer of data between the network computer system and the electronic data management system.

As described at page 2, final paragraph of the present application, the claimed invention provides for both data transfer to the device (e.g. disease management information for use by the patient) and from the device to the network (e.g. compliance information relating to the use of the device by the patient).

In accord with the claimed invention, data transfer is via wireless communications, and may therefore occur whilst the patient is ‘out and about’ or ‘on the move’ and without necessitating any specific visit to any particular fixed location. This is advantageous to the patient who may receive information as and when needed and without needing to call into the physician’s office.

Also in accord with the claimed invention, data transfer is also to a network computer system. This provides the physician with access to the network to both send information to the patient via the device and receive information therefrom at any location that enables network access. In one example, where the network is the Internet, such access could be provided by any computer that has Internet access capability. The physician is therefore not tied to any one workstation at a particular location. This is advantageous to the physician.

It is submitted from the offset, that none of the cited documents envisage or could provide for the advantages provided to both patient and physician by the claimed invention.

Withdrawal of the 103 rejections are therefore requested.

Applicant’s request withdrawal of the rejection of Claim 34 under 103(a). The examiner states that he takes “official notice” that “it is well known for doctors,

hospitals or other responsible parties to provide a means for monitoring the whereabouts of patients, since patients sometimes wander away from a designated area and become lost and/or disoriented, depending on their age or medical condition, and therefore it would have been obvious to one of ordinary skill in the art to put a "GPS device" with any of the devices disclosed in Bloomquist, Mishelevich et al., Davis et al or McKinnon et al."

The prior art medicament delivery systems having chronologs or the like mounted in or on the delivery device mentioned by the examiner all rely on appropriate patient input and operation for successful use of the device and the transmission of data. Lucidity is required to operate the device. As such, an independent tracking mechanism does not fill a need with these devices, because they would not be the kind of item used in treating the cognitively impaired. As such, absent the applicant's teachings in their application, there is no motivation at the time of filing to include a GPS system into a system as claimed in claims 34. The examiner's conclusion of obviousness inappropriately uses hindsight. Withdrawal of this rejection to claim 34 is requested.

In light of these amendments, all issues raised by the examiner to date have been addressed. As such, the claims are asserted to be in a condition for allowance. Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

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Respectfully submitted,

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EFD 6/11

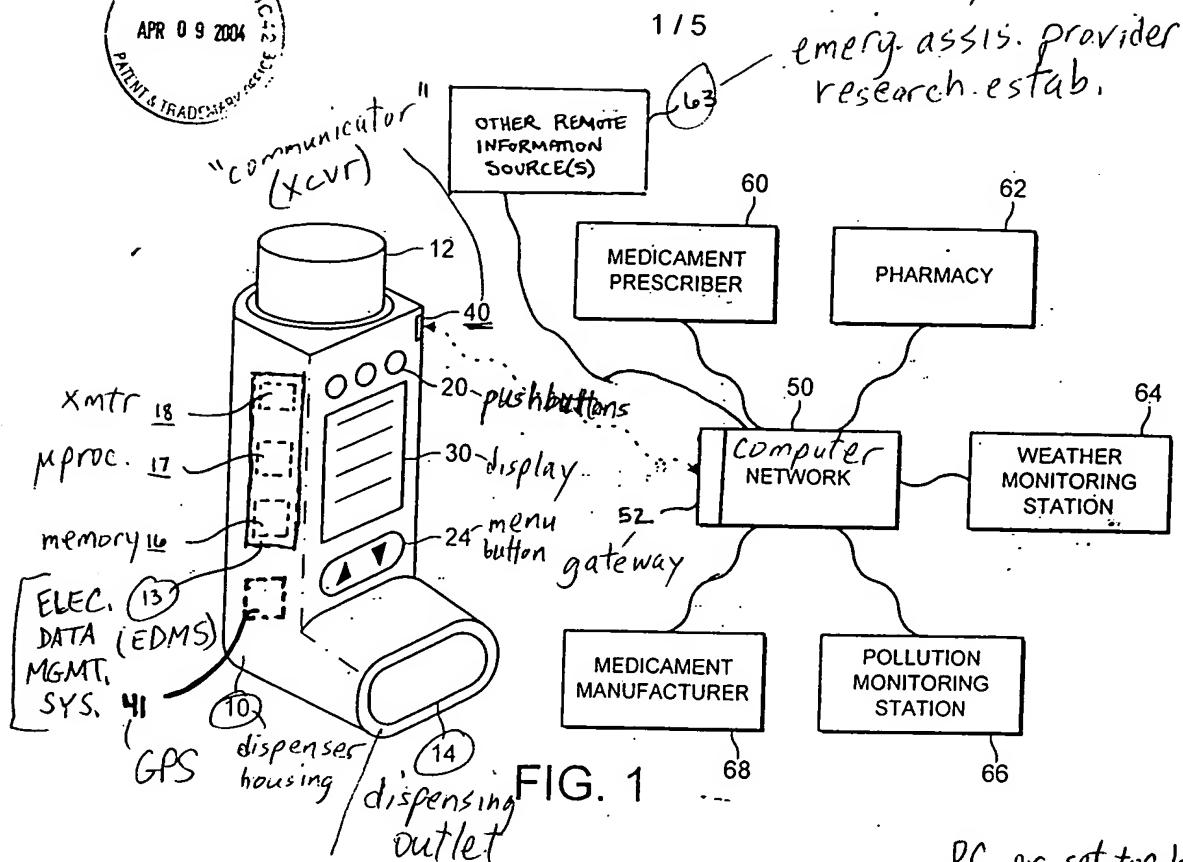
Docket No. PG3786USW

Applicant: Aspinwall et al.

Serial No. 10089,760 Attorney: Mike Strickland
Page 1 of 5

Reg. No. 35

Tel. No.: 919-433-9024



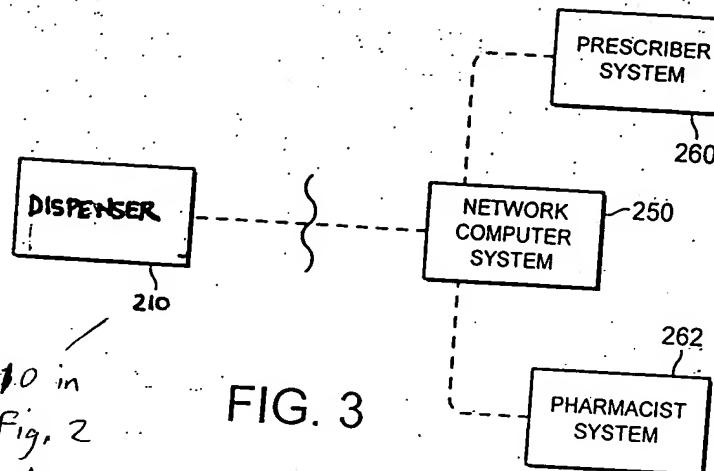


Docket No: PG3786USW

Applicant: Aetna et al.

Serial No: 10/030,760 Attorney: Mike Stickland Reg. No. 15 Tel. No: 919-433-2024
Page 2 of 5

215

110 in
Fig. 2incorporates
EDMS

13

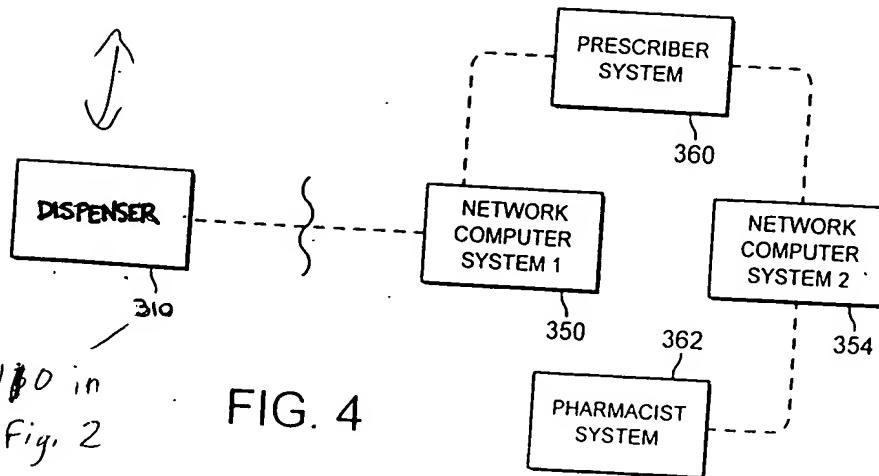
180 in
Fig. 2

FIG. 4



315

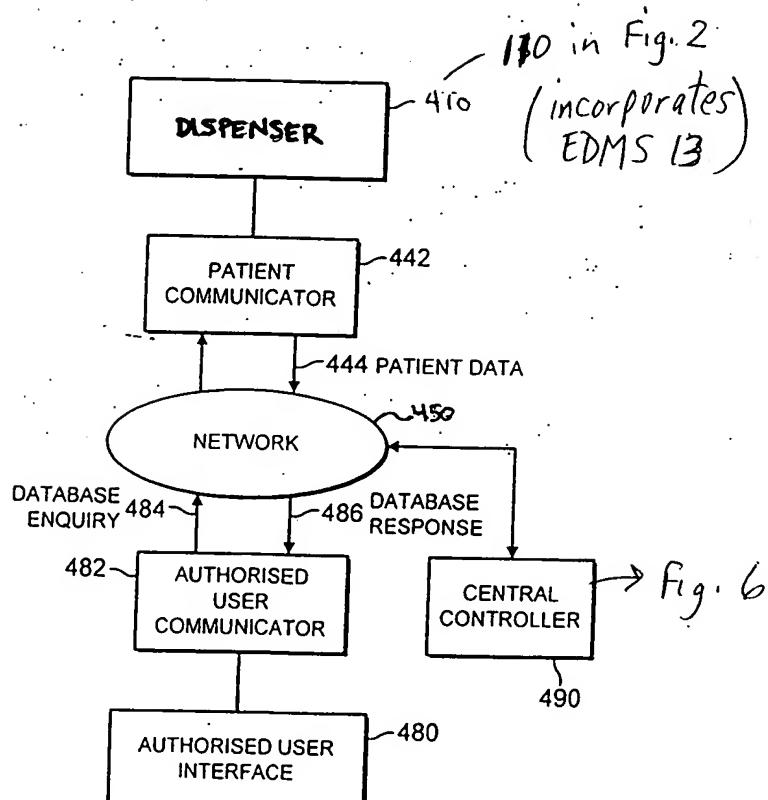


FIG. 5



415

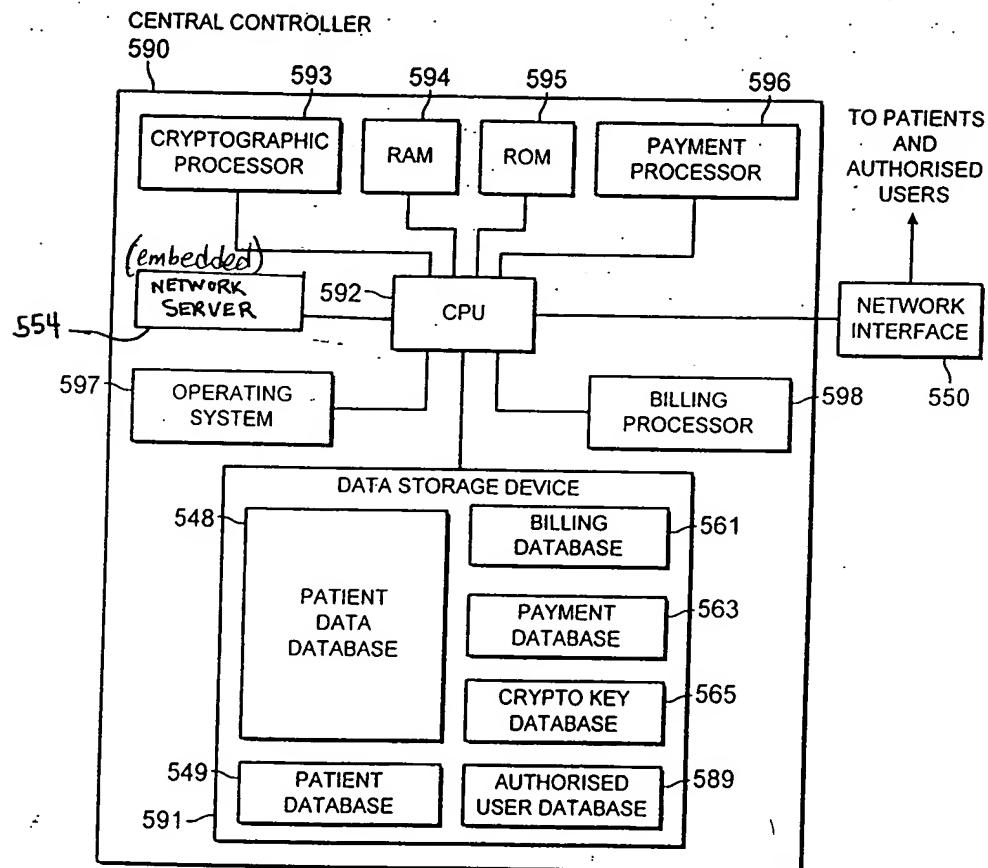


FIG. 6

@ central loc.



5/5

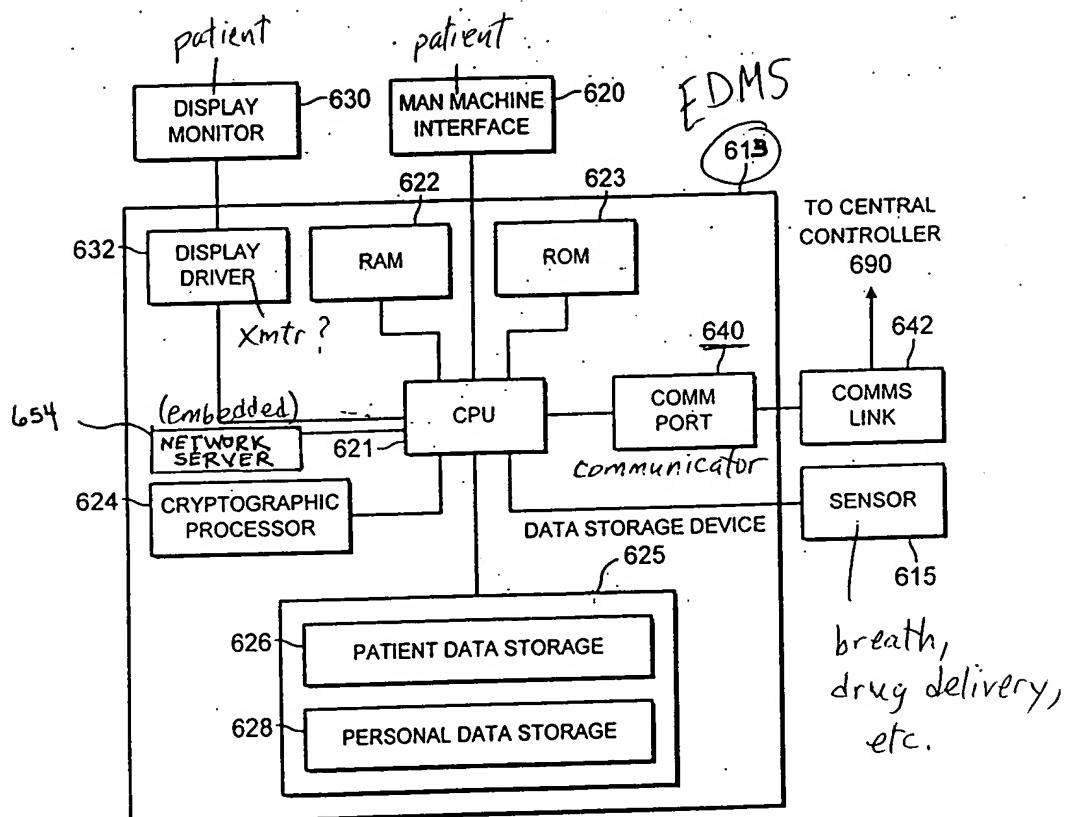


FIG. 7

① patient